

**B. 510(k) SUMMARY (as required by 21 CFR 807.92)****Aesculap® Implant Systems S4 Spinal System**  
*August 31, 2011*

**COMPANY:** Aesculap® Implant Systems, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 3005673311

**CONTACT:** Lisa M. Boyle  
610-984-9274 (phone)  
610-791-6882 (fax)

**TRADE NAME:** S4  
**COMMON NAME:** S4 Spinal System

**REGULATION NUMBER:** 888.3070 – Orthosis, Spinal Pedicle Fixation For Degenerative Disc Disease  
888.3070 – Orthosis, Spinal Pedicle Fixation  
888.3070 - Orthosis, Spondyloisthesis Spinal Fixation  
888.3050 – Appliance, Fixation, Spinal Fixation

**PRODUCT CODE:** NKB, MNI, MNH, and KWP  
**REVIEW PANEL:** Orthopedics

**PURPOSE FOR PREMARKET NOTIFICATION**

The S4 Spinal System described in this submission represents a line extension to the system. The purpose of the line extension is to add a new parallel rod connector.

**SUBSTANTIAL EQUIVALENCE**

Aesculap® Implant Systems, Inc. believes that the S4 Spinal System is substantially equivalent to the S4 Spinal System (K100623/K071945/K062085/K032219), and the Aesculap Spine System Evolution (K001080).

**DEVICE DESCRIPTION**

The S4 Spinal System consists of polyaxial screws and monoaxial screws of varying diameters and lengths, various hook styles, rods of varying lengths, and fixed and various styles of rod connectors. All implant components are top loading and top tightening. The S4 Spinal System is manufactured from Titanium and Titanium alloy in accordance with ISO 5832/3 and ISO 5832/2.

**INDICATIONS FOR USE**

The S4 Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation. Fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for treatment of the following acute and chronic instabilities or deformities:

- 1 ) degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- 2) spondylolisthesis,
- 3) trauma (i.e., fracture or dislocation),
- 4) spinal stenosis,
- 5) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- 6) tumor,
- 7) pseudoarthrosis, and
- 8) failed previous fusion.

**TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))**

The components of the Aesculap® Implant Systems S4 Spinal System are offered in similar shapes and sizes as the predicate devices. All the components are manufactured from Titanium and Titanium Alloy, which is the same material as the predicate devices.

**PERFORMANCE DATA**

As recommended by the FDA Guidance for Spinal System 510(k)'s, non-clinical testing was performed to demonstrate that the S4 Parallel Rod Connector is substantially equivalent to other predicate devices. The following testing was performed:

- Static Axial Compression Bending per ASTM 1717-11a
- Dynamic Axial Compression Bending per ASTM F1717-11a
- Static Torsion per ASTM 1717-11a

The results of these studies showed that the subject Aesculap S4 Parallel Rod Connector meets or exceeds the performance of the predicate devices, and the device is therefore found to be substantially equivalent.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

NOV 21 2011

Aesculap Implant Systems, Inc.  
% Ms. Lisa M. Boyle  
3773 Corporate Parkway  
Center Valley, Pennsylvania 18034

Re: K112551  
Trade/Device Name: S4 Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class III  
Product Code: NKB, MNH, MNI, KWP  
Dated: November 17, 2011  
Received: November 18, 2011

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

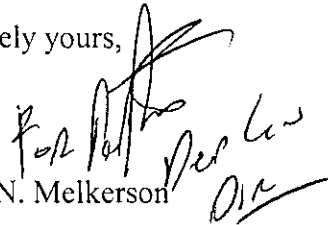
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**A. INDICATIONS FOR USE STATEMENT**

**510(k) Number:** K112551

**Device Name:** **S4 Spinal System**

**Indications for Use:**


The S4 Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation. Fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for treatment of the following acute and chronic instabilities or deformities:

- 1 ) degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- 2) spondylolisthesis,
- 3) trauma (i.e., fracture or dislocation),
- 4) spinal stenosis,
- 5) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- 6) tumor,
- 7) pseudoarthrosis, and
- 8) failed previous fusion.

Prescription Use   X   and/or Over-the-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K11 2551